JAN 2 4 2013

SECTION 2	510(k) SUMMARY
510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.
Submitter	PuriCore Inc. 508 Lapp Road Malvern, PA 19355
Contact Person	Art Morse Director Quality Assurance and Regulatory Affairs PuriCore Inc. 508 Lapp Road Malvern, PA 19355 484 321 2728 (O), 484 321 2704 (F), 610 306 2870 (C)
Date Prepared	September 24th, 2012
Trade Name	Vashe® Skin & Wound Hydrogel
Common Name	Hydrogel Wound Dressing
Classification Name	Dressing, wound and burn drug/hydrogel
Predicate Devices	Epicyn™ HydroGel, Oculus Innovative Sciences, Inc., K102945, February 2nd, 2011.
Device Description	Vashe® Skin and Wound Hydrogel is an emollient containing, non oily hydrogel. The gel forms a protective barrier which retains moisture and provides relief of the burning and itching experienced with various dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis. The Hydrogel when applied to diseased skin forms a protective barrier that helps to maintain a moist wound and skin environment. The product contains hypochlorous acid as a preservative. The Hydrogel will be supplied in plastic tottles as described in Section 3.2. The device is presented as a prescription product that requires the physician to diagnose the disease state and prescribe the product.
Intended Use	**Vashe® Skin and Wound Hydrogel – For Professional Use Only** Under the supervision of a health care professional, Vashe® Skin and Wound Hydrogel is indicated for the management and relief of pain, burning and itching experienced with various dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis, as well as for the relief of pain from first and second degree burns, and aids to relieve dry waxy skin by maintaining a moist wound and skin environment. A moist wound and skin environment is beneficial to the healing process. These indications are similar to the predicate device, Epicyn™ Hydrogel, K102945 cleared on February 2011.
Summary of Technological Characteristics Compared to the Predicate Device	Vashe® Skin and Wound Hydrogel is an aqueous based topical hydrogel which controls moisture and wound exudates. Hydrogel characteristics are imparted by an inert viscosity controlling agent and emollient. Vashe® Skin and Wound Hydrogel maintains a moist wound environment that supports the wound healing process by encouraging autolytic debridement. The hydrogel barrier manages pain and itch by protecting the wound from contamination and irritation.

	Vashe® Skin and Wound Hydrogel is similar in function and has the same intended use as the predicate device Epicyn™ HydroGel legally marketed via 510(k) K102945 (Atrapro Antipruritic Hydrogel).
Test & Conclusions	Vashe® Skin and Wound Hydrogel has been subjected to *in-vivo* and *in-vitro* biocompatibility testing to ISO-10993 standards and. These results demonstrate that Vashe® Skin and Wound Hydrogel is safe for use when in contact with abraded, breached or compromised skin. Furthermore, we have concluded that Vashe® Skin & Wound Hydrogel at its minimum recommended concentration demonstrates effective preservative activity and supports a preservative claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

January 24, 2013

PuriCore Inc.
% Mr. Art Morse
508 Lapp Road
Malvern, Pennsylvania 19355

Re: K123071
Trade/Device Name: Vashe® Skin and Wound Hydrogel
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 20, 2012
Received: December 21, 2012

Dear Mr. Morse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PuriCore
Pure Science. Pure Life.

K123071

Indications for Use Statement

510(k) Number:

Device Name: Vashe® Skin and Wound Hydrogel

Indications for Use:

Vashe® Skin and Wound Hydrogel – For Professional Use Only
Under the supervision of a health care professional, Vashe® Skin and Wound Hydrogel is indicated for the management and relief of pain, burning and itching experienced with various dermatoses, including atopic dermatitis, allergic contact dermatitis and radiation dermatitis, as well as for the relief of pain from first and second degree burns, and aids to relieve dry waxy skin by maintaining a moist wound and skin environment. A moist wound and skin environment is beneficial to the healing process.

Prescription Use XX (Part 21 CFR 801 Subpart D) OR Over-The-Counter Use: ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDHR, Office of Device Evaluation (ODE)

Jiyoung Dang

(Division Sign-Off)
Division of Surgical Devices
510(k) Number K123071